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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FOX, DAVID T.

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,208

Applicant(s)

FABIJANSKI ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98-110 and 112-120 is/are pending in the application.
- 4a) Of the above claim(s) 100, 102, 107, 108 and 114-119 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 98-99, 101, 103-106, 109-110, 112-113, 120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' amendments of 09 June 2003 and accompanying arguments have overcome the objection to the specification and the outstanding rejections of the claims under 35 USC 112, first paragraph. Since the non-initialed and non-dated alterations were merely instructions regarding the typeface or font used to print nucleotide sequences, rather than any change in sequence, the requirement for a supplemental oath has been withdrawn.

This application contains claims 100, 102, 107-108 and 114-119 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim 120 (newly submitted) is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn to the use of any "derivative", of any sequence and encoding a protein of any sequence and function, of particular oncogenes from *Agrobacterium*. In contrast, the specification only provides guidance for the native oncogenes from *Agrobacterium* which encode the native proteins. No guidance is provided regarding the identification or isolation of these oncogenes from any other _____

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organism, or for the alteration of the oncogenes' nucleotide sequence in order to produce a multitude of non-exemplified proteins of a multitude of non-exemplified functions. No guidance is provided regarding the domains necessary to retain in order to retain oncogene product function and repressor activity.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

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Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claims 98-99, 103, 109-110 and 112-113 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mariani et al (U.S. 5,689,041), as stated on page 7 of the last Office action.

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Claims 98-99, 103-104, 109-110 and 112-113 remain rejected under 35 U.S.C. 102(e) as being anticipated by Mariani et al (U.S. 5,723,763 effectively filed March 1994), as stated on pages 8-9 of the last Office action.

Claims 98-99, 103-104, 106, 109-110 and 112-113 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/44465 (MONSANTO), as stated on pages 9-10 of the last Office action.

Claims 98-99, 101, 103, 109-110 and 112-113 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mariani et al (U.S. 5,689,041), as stated in the last Office action on pages 10-11.

Claims 98-99, 101, 103-106, 109-110 and 112-113 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mariani et al (U.S. 5,723,763 effectively filed March 1994).

Claims 98-99, 101, 103-106, 109-110 and 112-113 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/44465 (MONSANTO), as stated on pages 12-13 of the last Office action.

Claim 120 is deemed free of the prior art, given the failure of the prior art to teach or suggest plant transformation with an *Agrobacterium* oncogene and a gene which represses the activity of the oncogene product.

Amendment of claim 120, part (b)(i), line 3 to insert -- and-- after "*Agrobacterium*", and to delete the phrase " , and derivatives of any thereof" in line 4, would result in allowance of that claim.

No claim is allowed.

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Applicant's arguments filed 09 June 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive. Applicants urge that the art rejections under 35 USC 102 are improper, given the failure of the cited references to teach independent segregation of the lethal gene and the repressor, the failure of MONSANTO to reduce to practice the inhibition of the lethal gene product, and the failure of the Examiner to establish inherency.

The Examiner maintains that the cited references teach a method which encompasses all of the claimed method steps, wherein independent segregation would naturally occur in some transformed plants which had been selected, as discussed in the last Office action. It is noted that Applicants have not demonstrated any actual determination of independent segregation. Thus, the Examiner is unable to determine that Applicants' invention is distinguished over the prior art, and Applicants' comments on page 12 of the amendment regarding MONSANTO are unpersuasive.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993), which teaches that a reference teaching a claimed process, wherein one of the claimed properties of a product used in the prior art process is inherent but undisclosed by the reference, may be properly applied as art against the claimed process.

Applicants urge that the obviousness rejections are improper, given the failure of the cited references to teach or suggest the claimed method, wherein the prior art methods actually teach away from the claimed method.

The Examiner maintains that the method steps are all taught or suggested, as stated in the last Office action. The Examiner further maintains that Applicants have not provided any evidence of reduction to practice of all of their method steps, and so have not provided any evidence of unexpected results which would distinguish the claimed invention from the teachings of the prior art.

See *In re Kuhle*, 188 USPQ 7, (CCPA 1975), which teaches that a feature which solves no stated problem and which presents no unexpected results would have been an obvious matter of choice.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 6, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a large, stylized initial "D" and "F".